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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,903	03/10/2004	Yuji Yamamoto	25142-0002001	3373

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FISH & RICHARDSON P.C.
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EXAMINER

PAGONAKIS, ANNA

ART UNIT	PAPER NUMBER
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1628

NOTIFICATION DATE	DELIVERY MODE
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09/01/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/797,903	Applicant(s) YAMAMOTO ET AL.	
	Examiner ANNA PAGONAKIS	Art Unit 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12, 14, 16-18 and 20-37 is/are pending in the application.
- 4a) Of the above claim(s) 16, 21, 28 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 14, 17, 18, 20, 22-27, 29-34, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5 sheets; 7/1/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment filed 7/1/2010 has been received and entered into the present application.

As reflected by the attached completed copy form PTO/SB/08A (five pages total), the Examiner has considered the cited references. Documents not published in the English language were not considered.

Applicant's arguments filed 7/1/2010 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Status of Claims

Claims 12, 14, 16-18 and 20-37 are pending.

Claims 16, 21, 28 and 35 remain withdrawn.

Claims 12, 14, 17-18, 20, 22-27, 29-34, 36 and 37 are currently under examination and the subject matter of the present Office Action.

New grounds of rejection upon further consideration:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of

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each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a)

Claims 12, 14, 17-18, 20, 22-27, 29-34 and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Funahashi et al. (WO 02/032872, cited by Applicant) as evidenced by CancerCare, (www.lungcancer.org, 2009; of record) and in view of Micke et al. (Clinical Cancer Research, vol. 9, 188-194, January 2003).

Examiner is using the Japanese WO 02/032871 document for its publication date and is providing US Patent 7, 253, 286 as an English language equivalent of that document.

Funahashi et al. discloses a method of treating lung cancer (column 22) comprising administration of the elected compound: claim 1 discloses R_1 and R_2 as hydrogen (claim 1), R^{a12} is the cyano taught by the formula in column 904, line 40, second compound, (claim 1), Y^{a1} is represented by the formula in column 903, line 35, first compound, where W^{31} and W^{32} are each independently an optionally substituted carbon atom (claim 1) and Z^{12} is an alicyclic hydrocarbon group (claim 1). Further, the compound can be administered orally and parenterally (column 83, lines 23-29).

Funahashi et al. is silent on determining of the patient's cancer expresses c-kit of a mutant c-kit kinase.

CancerCare teaches that there are two types of lung cancer, non-small cell lung cancer and small cell lung cancer (SCLC).

Micke et al. teaches that c-kit represents a new prognostic factor in SCLC.

One of ordinary skill in the art would have found it prima facie obvious at the time of the invention to determine whether the patient's cancer expresses c-kit kinase with administration of an anticancer agent known for the treatment of SCLC because c-kit kinase is known to be a prognostic

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indicator for SCLC. One would have been motivated to do so in order to confirm that a patient has SCLC.

Claims 12, 14, 17-18, 20, 22-27, 29-34 and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Funahashi et al. (WO 02/032872, cited by Applicant) as evidenced by CancerCare, (www.lungcancer.org, 2009; of record) and in view of Sekido et al. (Cancer Research, 51, 2416-2419, May 1, 1991).

Examiner is using the Japanese WO 02/032871 document for its publication date and is providing US Patent 7, 253, 286 as an English language equivalent of that document.

Funahashi et al. discloses a method of treating lung cancer (column 22) comprising administration of the elected compound: claim 1 discloses R_1 and R_2 as hydrogen (claim 1), R^{a12} is the cyano taught by the formula in column 904, line 40, second compound, (claim 1), Y^{a1} is represented by the formula in column 903, line 35, first compound, where W^{31} and W^{32} are each independently an optionally substituted carbon atom (claim 1) and Z^{12} is an alicyclic hydrocarbon group (claim 1). This particular combination teaches the compound elected by Applicant. Further, the compound can be administered orally and parenterally (column 83, lines 23-29).

Funahashi et al. is silent on determining if the patient's cancer expresses c-kit of a mutant c-kit kinase.

CancerCare teaches that there are two types of lung cancer, non-small cell lung cancer and small cell lung cancer (SCLC).

Sekido et al. teaches that c-kit expression in SCLC reflects the unique biological nature of the tumor cells different from non-SCLC.

One of ordinary skill in the art would have found it prima facie obvious at the time of the invention to determine whether the patient's cancer expresses c-kit kinase with administration of an

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anticancer agent known for the treatment of SCLC because c-kit kinase is known to be expressed in SCLC cells and further distinguishes from other tumor cells which are non-SCLC. One would have been motivated to do so in order to confirm that a patient has SCLC.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 7am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Brandon J Fetterolf/
Supervisory Patent Examiner, Art Unit 1628